WHO's Evidence-Based Guidelines for Family Planning

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TRAINING
IN RESEARCH IN
REPRODUCTIVE HEALTH
2005

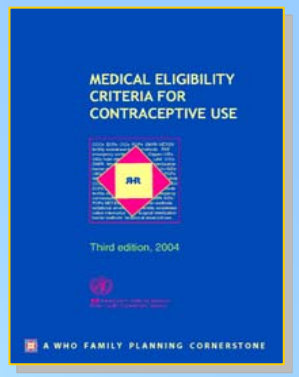
World Health Organization
Department of Reproductive Health and Research

What option would you prefer?

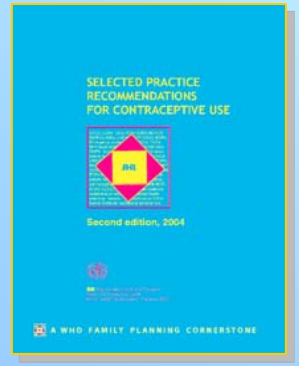
Faith Versus Facts

The Four Cornerstones of evidence-based guidance

Medical Eligibility Criteria for Contraceptive Use

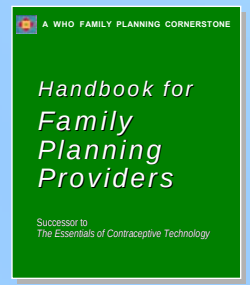


Selected Practice Recommendations for Contraceptive Use



Guidelines for policy-makers and programme managers

Tools for health-care providers



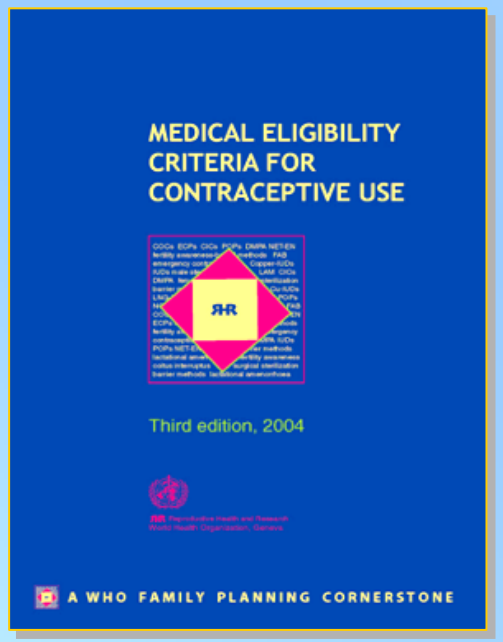
Decision-Making Tool for Family Planning Clients and Providers

Handbook for Family Planning Providers

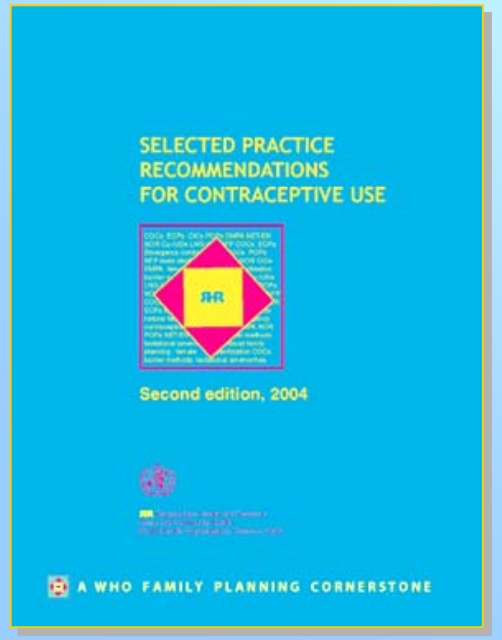
Why are the Four Cornerstones needed?

- To base family planning practices on the best available evidence
- To set global standards of care
- To improve quality of care

The Evidence-Based Guidelines



Who can use contraceptive methods



How to use contraceptive methods

The WHO Guidance on FP

- Based on Evidence
- Developed Through Consensus
- Updated Continuously

Guidance based on evidence

- Adherence to WHO ‘Guidelines for Guidelines’
- Systematic reviews of evidence
- Citations of evidence used for decision-making

Guidance based on evidence and kept up-to-date

Monitoring all new evidence

CIRE

Systematic review on selected issues

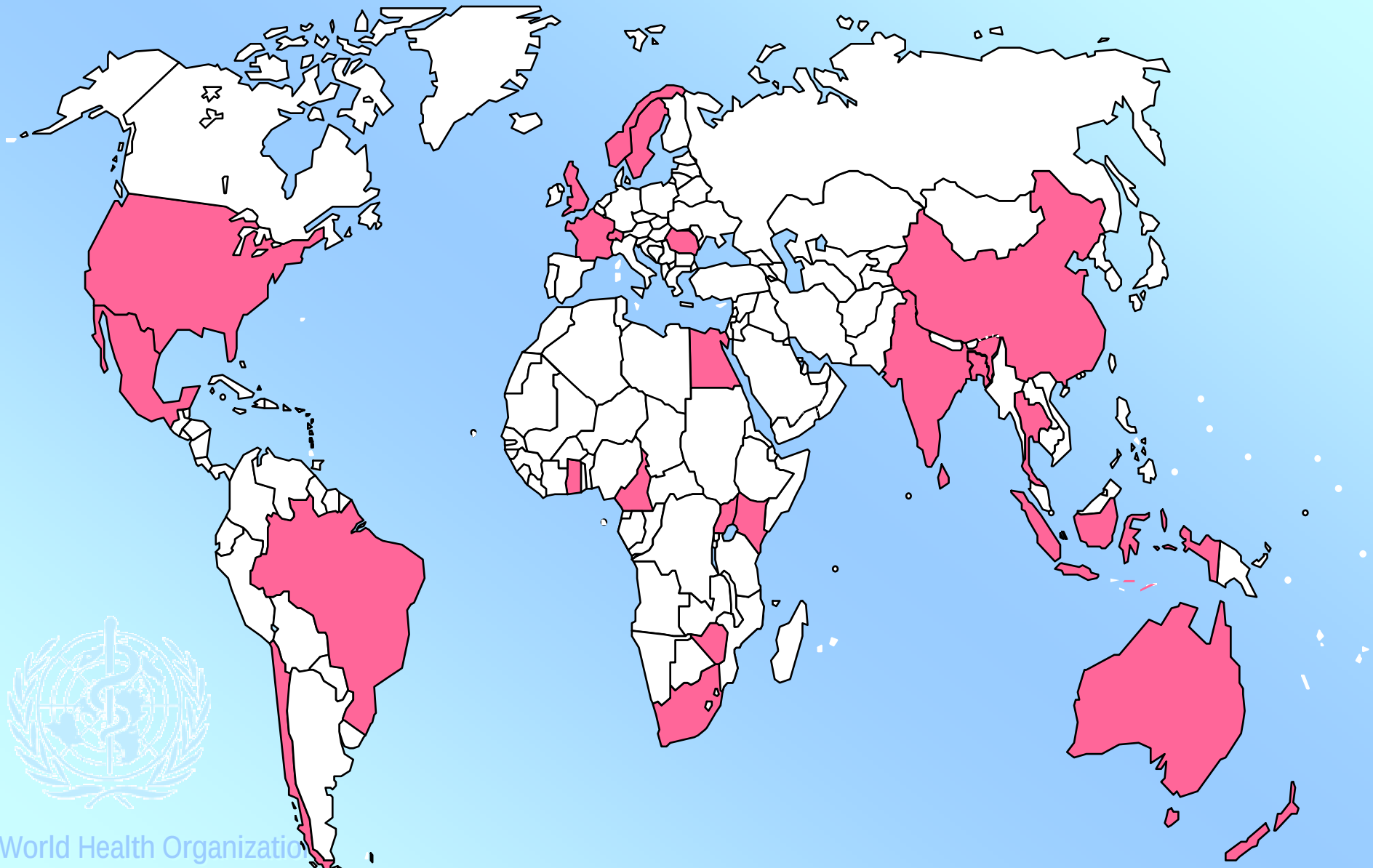
Expert Working Groups

Guidance developed through consensus

Expert Working Group meetings:

- Country experts
- Representatives of:
  - UNFPA
  - World Bank
  - IPPF
  - USAID
  - CDC
  - NICHD
  - Engender Health
  - FHI
  - JHU/CCP
  - JHPIEGO
  - IntraHealth
  - Georgetown University Medical Center
  - Management Sciences for Health

Country experts



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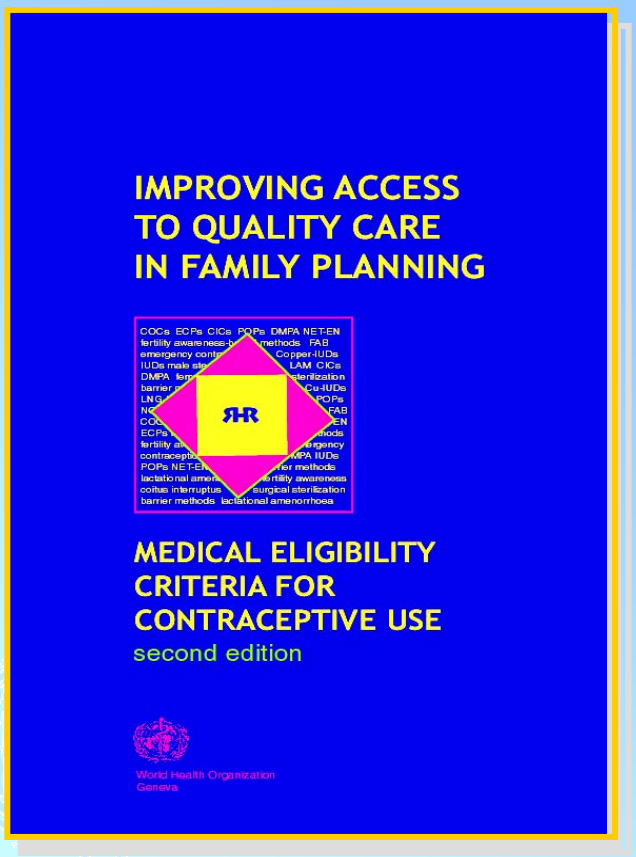
On-going
Monitoring and Updating

- 1996: First publication of Medical Eligibility Criteria for Contraceptive Use
- 2nd edition published 2000
- 3rd edition in print
- Continuous improvement in methodology

Medical Eligibility Criteria for Contraceptive Use



- Addresses large gap in family planning guidance for women with medical problems or other special conditions
- Gives over 1700 recommendations on *who* can use contraceptive methods

Condition Classification Categories

1. No restriction for the use of the contraceptive method
2. The advantages of using the method generally outweigh the theoretical or proven risks
3. The theoretical or proven risks usually outweigh the advantages of using the method
4. An unacceptable health risk if the contraceptive method is used

Simplified Classification of Conditions

Classification	With Clinical Judgement	With Limited Clinical Judgement
1	Use method in any circumstance	Yes
2	Generally use the method	Yes
3	Use of the method not usually recommended unless other more appropriate methods are not available or not acceptable	No
4	Method not to be used	No

Methods of contraception

- Combined oral contraceptives
- Combined hormonal contraceptives (1 month injectables, patch, vaginal ring)
- Progestogen-only contraceptives (pills, implants, 2-3 month injectables)
- Emergency contraceptive pills
- IUDs (copper bearing and levonorgestrel)
- Emergency IUD
- Barrier methods (condoms, spermicides & diaphragm)
- Fertility awareness-based methods
- Lactational amenorrhoea (LAM)
- Coitus Interruptus
- Sterilization (male and female)

Identification of conditions

Conditions represent either:

- an individual's characteristics (e.g. age, parity, breastfeeding), or
- a known pre-existing medical condition (e.g. hypertension, STI, diabetes)

Medical Eligibility Criteria

Example table: Smoking and Contraceptive Use

CONDITION	COC	CIC	P/R	POP	NET-EN DMPA	LNG/ETG Implants	Cu-IUD	LNG-IUD
SMOKING								
a) Age<35	2	2	2	1	1	1	1	1
b) Age≥35								
(i) <15 cigarettes/day	3	2	3	1	1	1	1	1
(ii) ≥15 cigarettes/day	4	3	4	1	1	1	1	1

Medical Eligibility Criteria

Summary tables 2004: STIs and IUD Summary

CONDITION	Cu-IUD		LNG-IUD	
	I	C	I	C
STIs				
a) Current purulent cervicitis or chlamydial infection or gonorrhoea	4	2*	4	2*
b) Other STIs (excluding HIV and hepatitis)	2	2	2	2
c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	2	2	2	2
d) Increased risk of STIs	2/3**	2	2/3**	2

Clarifications:

* Treat the STI using appropriate antibiotics. There is usually no need for removal of the IUD if the client wishes to continue its use.

**Very high individual likelihood of exposure to gonorrhoea and chlamydia.

Case scenario 1

An 36 year old woman with three children comes to the health centre requesting oral contraceptives. She tells you she smokes 10 cigarettes per day.

A) Are oral contraceptives medically appropriate for her?

B) Does she have any other highly effective temporary contraceptive options?

Case scenario 1: the answer

A) Oral contraceptives are usually not appropriate for women who smoke over 35 unless other methods are not available or acceptable.

Women over 35 who smoke more than 15 cigarettes per day or more should not use combined oral contraceptives.

B) This client is medically eligible to use combined injectables, progestogen-only contraceptives, and IUDs.

Case Scenario 2

A 25 year old woman has just given birth and plans to breastfeed. She would like an injection for contraception prior to returning home.

Which of the following options is medically appropriate?

A) A combined injectable contraceptive provided immediately

B) A combined injectable contraceptive provided at six weeks postpartum

C) A progestogen-only injectable contraceptive provided immediately

D) A progestogen-only injectable contraceptive provided at 6 weeks postpartum

Case scenario 2: the answer

D) A progestogen-only injectable contraceptive provided at 6 weeks postpartum.

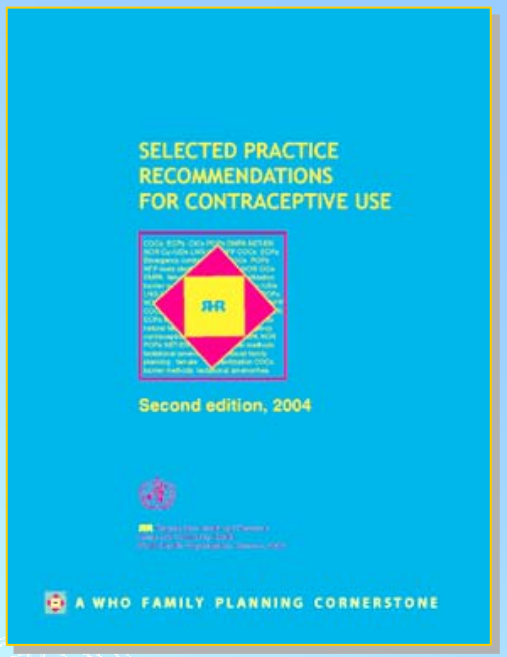
Comment

- **Combined injectables are not medically appropriate in breastfeeding women prior to 6 weeks postpartum, and generally should not be used until after 6 months postpartum.**
- **Progestogen-only injectables are medically appropriate in breastfeeding women at 6 weeks postpartum.**
- **Neonate may be at risk of exposure to steroid hormones during the first six weeks postpartum.**

Global impact of the Medical Eligibility Criteria

- Translated into 8 languages
- Impact on guidelines in over 50 countries
- Integrated into popular texts

Selected Practice Recommendations for Contraceptive Use



- **2002: First publication of *Selected Practice Recommendations for Contraceptive Use***
- **2005: 2nd Edition in print**
- **33 selected questions on *how* to use contraceptive methods**

Topics for the Questions

- Initiation/Continuation of methods
  - When to start?
  - When to readminister?
- Incorrect use - missed pills
- Problems during use
  - Vomiting and or diarrhoea
  - Menstrual abnormalities (progestogen-only methods and IUDs)
  - Pelvic inflammatory disease
  - Pregnancy
- Programmatic Issues:
  - What exams or tests should be done routinely
  - Follow-up
  - How to be reasonably sure a woman is not pregnant

Selected Practice Recommendations

For each question:

- Working Group's recommendations for key situations
- Comments by the Working Group
- Key unresolved issues
- Information about the evidence
  - Literature search question
  - Level of evidence
  - References identified by systematic review

Example: When can a woman start COCs?

Having menstrual cycles

- She can start COCs within 5 days after the start of her menstrual bleeding. No additional contraceptive protection is needed.
- She can also start COCs at any other time, if it is reasonably certain that she is not pregnant.
  If it has been more than 5 days since menstrual bleeding started, she will need to abstain from sex or use additional contraceptive protection for the next 7 days.

When can a woman start COCs?

Working Group comments:

- Risk of ovulation within the first 5 days of the cycle is low.
- Suppression of ovulation was less reliable when starting COCs after day 5.
- 7 days of continuous COC use was necessary to reliably prevent ovulation.

When can a woman start COCs?

Key unresolved issues

- **Does starting each pill pack on a specific day of the week increase correct COC use?**

Evidence

- **Level II-1**
- **Indirect**

Routine exams or tests

Class A = essential and mandatory in all circumstances for safe and effective use of the method

Class B = contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context.

Class C = does not contribute substantially to safe and effective use of the method

Routine exams or tests

Exam or screening	Hormonal methods	IUD	Condoms / Spermicide	Female sterilization
Breast exam	C	C	C	C
Pelvic exam	C	A	C	A
Cervical cancer	C	C	C	C
Routine lab tests	C	C	C	C
Haemoglobin	C	B	C	B
STI risk assessment	C	A	C	C
STI screening	C	B	C	C
Blood pressure	**	C	C	A

Class A: essential and mandatory in all circumstances

Class B: contributes substantially to safe and effective use

Class C: does not contribute substantially to safe and effective use

How to be reasonably sure a woman is not pregnant

No signs and symptoms of pregnancy AND

Meets any of the following criteria:

- No intercourse since last normal menses
- Correctly and consistently using reliable method of contraception
- Within the first 7 days after normal menses
- Within 4 weeks postpartum for non-lactating women
- Within 7 days post-abortion or post-miscarriage
- Fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months postpartum

Case Scenario 1

A woman comes to the clinic requesting combined oral contraceptives on day 7 of her menstrual cycle. She has not had sexual intercourse since the first day of her menstrual period.

Which of the following is medically appropriate?

A) advise her to return to clinic on the first day of her next menstrual period.

B) provide her with pills and tell her that she can start now without any further precautions.

C) provide her with pills and tell her that she can start now ,but should abstain from sex or use additional contraceptive protection for the next 7 days.

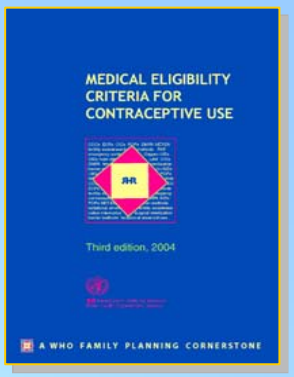
Case Scenario 1: the answer

C) provide her with pills and tell her that she can start now ,but should abstain from sex or use additional contraceptive protection for the next 7 days.

Suppression of ovulation was considered to be less reliable when starting after day 5 or during amenorrhoea, seven days of continuous COC use was deemed necessary to reliably prevent ovulation.

Keeping the guidance up-to-date

Medical Eligibility Criteria for Contraceptive Use



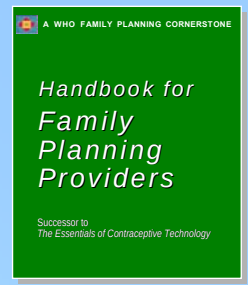
Selected Practice Recommendations for Contraceptive Use

Guidelines for policy-makers and programme managers

System for keeping the guidance up-to-date

CIRE

Tools for health-care providers



Decision-Making Tool for Family Planning Clients and Providers

Handbook for Family Planning Providers

CIRE CONTINUOUS IDENTIFICATION OF RESEARCH EVIDENCE

NEW EVIDENCE FOR CONTRACEPTIVE USE

FOR THE WORLD HEALTH ORGANIZATION MEDICAL ELIGIBILITY CRITERIA (MEC) AND SELECTED PRACTICE RECOMMENDATIONS (SPR)

Welcome to CIRE - the Continuous Identification of Research Evidence - a collaborative effort of the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), and the Johns Hopkins Bloomberg School of Public Health's Center for Communication Programs (CCP).

To ensure that its evidence-based family planning guidance remains current, the WHO collaborates on the CIRE system with the WHO Collaborating Centre in Reproductive Health at the CDC and the INFO Project at CCP. The system is supported by the United States Agency for International Development (USAID) and the National Institute of Child Health & Human Development (NICHD).

The CIRE system facilitates the updating of WHO's evidence-based family planning guidance. The system identifies articles whose study objectives concern a topic addressed by WHO's Medical Eligibility Criteria for Contraceptive Use (MEC) or the Selected Practice Recommendations for Contraceptive Use (SPR). Identification begins with screening of new articles entered into the POPLINE database since January 2002. These articles are then reviewed to determine whether the evidence they provide is relevant to WHO guidance. Any updates to current guidance based on evidence from the CIRE system will be noted on the electronic versions of the MEC or SPR. Changes to classifications of the MEC or recommendations in the SPR will ordinarily be made only following expert working group meetings.

The new articles that have been identified to date are accessible by searching the CIRE system and are also available through a regular email bulletin.

- Send this email to receive regular CIRE system postings from the email bulletin

WHO's on-line versions of the MEC and the SPR also feature the availability of new articles identified by the CIRE system. In addition, new postings to the CIRE system will be featured in CCP's weekly e-zine, The Pop Reporter. You may visit POPLINE for more information on obtaining full-text articles from CCP or view the WHO Family Planning Page for more information about family planning guidance.

SEARCH EVIDENCE

Medical Eligibility Criteria (MEC):

Choose a Method **AND/OR** Choose a Condition **Search**

Implementation of system for Keeping the Guidance Up-to-date

Key Elements:

- Identification of potentially relevant new evidence, as it becomes available
- Critical appraisal of relevant new evidence
- Evaluation of impact of new evidence on guidance
- Preparation of systematic reviews

Family Planning

Family planning
Safety & effectiveness
New & improved methods
Service delivery

Resources
Family planning materials
Other reproductive health resources

Unmet needs

There are still some 123 million women around the world, mostly in developing countries, who are not using contraception in spite of an expressed desire to space or limit the numbers of their births.[1]

An estimated 38% of all pregnancies occuring around the world every year are unintended, and around 6 out of 10 such unplanned pregnancies result in an induced abortion.[2]

A woman's ability to space or limit the number of her pregnancies has a direct impact on her health and well-being as well as the outcome of her pregnancy. In enabling women to exercise their reproductive rights, family planning programmes can also improve the social and economic circumstances of women and their families.

WHO's role in promoting FP

The reasons why family planning needs are often not met are varied, but include: poor access to quality services, a limited choice of methods, lack of information, concerns about safety or side-effects and partner disapproval.

WHO is currently addressing some of these needs in working to help

- improve the safety and effectiveness of contraceptives methods;
- widen the range of family planning methods available to women and men;
- improve the quality of family planning service delivery.

Evidence-based guidance

The Medical Eligibility Criteria for Contraceptive Use

Selected Practice Recommendations for Contraceptive Use

The CIRE System to ensure that family planning guidance remains current.

Guidance updates

DMPA and bone mineral density

- **Loss of bone mineral density has been a concern for younger and older women**
- **2 new long-term studies by Pfizer, on older women and adolescents**
- **Statements issued by the US Food and Drug Administration (FDA) and the UK Committee on Safety of Medicines (CSM) in November 2004**

DMPA and bone mineral density

US FDA Statement

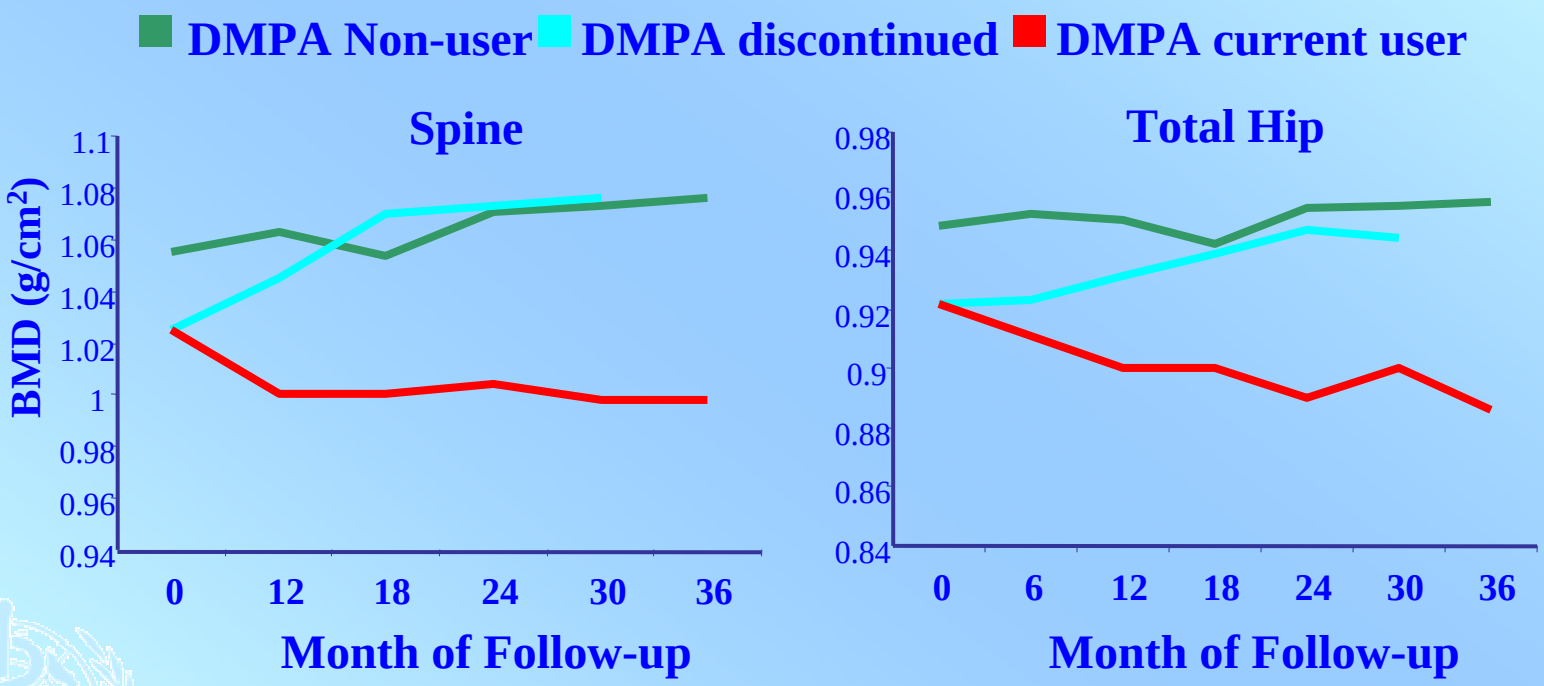
- **DMPA should only be used as a long-term method (longer than 2 years) only if other methods are inadequate**
- **DMPA can pose additional risk in women with risk factors for osteoporosis**

DMPA and bone mineral density

UK CSM Statement

- **Adolescents may use DMPA only if other methods are considered unsuitable or unacceptable**
- **Careful re-evaluation of risks and benefits should be assessed for women of all ages who wish to continue DMPA for more than 2 years**
- **Women with risk factors for osteoporosis should consider other methods of contraception**

Changes in bone mineral density among 182 DMPA users and 258 non-users, 18-39 years old



Source: Scholes et al, 2002

DMPA and bone mineral density

- **WHO current recommendations**
  - **Age <18 years - category 2**
  - **Age 18-45 years - category 1**
  - **Age >45 years - category 2**
- **WHO's response:**
  - **Systematic review updated and reviewed by the Guidelines Steering Group**
  - **No consensus yet on how the new evidence would change current recommendations**
  - **Interim statement to be posted on the web**
  - **Technical consultation planned for June 2005 with researchers and bone health experts**

Hormonal methods and STIs

- Morrison et al. study comparing the risk of STIs among users of DMPA, COCs and non-hormonal methods
- COC users: no statistically significant increased risk of acquiring chlamydia or gonorrhoea
- DMPA users: a 3.6-fold increased risk of chlamydia or gonorrhoea

Hormonal methods and STIs

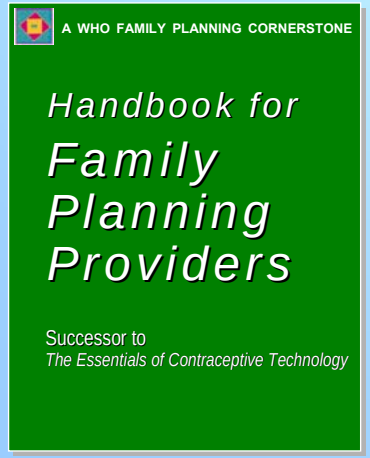
- **WHO current recommendation for DMPA and COCs**

  Women at high risk for STIs → Category 1

- **WHO's response:**
  - **Systematic review updated and reviewed by the Guidelines Steering Group**
  - **Concluded that there is no need for a change in the current WHO recommendation**
  - **Further research is needed**

Tools for health care providers

Decision-Making Tool for Family Planning Clients and Providers



Handbook for Family Planning Providers

Decision-making Tool: A multi-purpose tool

- Decision-making tool
- Problem-solving tool
- Job-aid
- Reference guide
- Training tool

Decision-making Tool for Family Planning Clients and Providers

- A tool for primary and secondary level FP providers and their clients
- Facilitates the interaction between the client and the provider
- Promotes informed choice of a contraceptive method
- Adaptable to local contexts

Best Practices in Client-Provider Interaction

Do you have a method in mind?

If you do, let's talk about how well it suits your needs

- **What have you heard about it?**
- **What do you like about it?**

If not, we can find a method right for you

Important for choosing a method:

*Do you need protection from pregnancy **AND** sexually transmitted infections?*

Evidence-Based Technical Information

If you miss pills

ALWAYS:

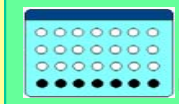
1. Take a pill as soon as you remember
2. Take the next pill at the usual time
3. Continue to take your pill as usual, one each day

4. If you miss 2 or more pills, or start pack 2 or more days late, you ALSO need to:

USE BACK-UP:
Avoid sex or use condoms for 7 days

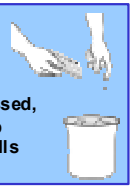
AND

SKIP WEEK 4:
(inactive pills or pill-free week)
and go straight to next pack

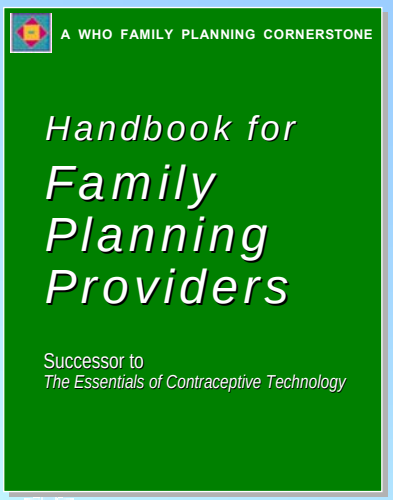


Special rule for Inactive Pills
(28 day packs only!)

THROW AWAY pills that were missed, and keep taking pills as usual



NEW – UNDER DEVELOPMENT!
Handbook for Family Planning Providers



- Successor to 'The Essentials of Contraceptive Technology' (JHU/CCP)
- To be published in 2005
- To contain all WHO FP guidance

The Handbook for Family Planning Providers

World Health Organization
Department of Reproductive Health and Research

The Handbook for Family Planning Providers

A product being developed through collaboration with key IBP partners, including:

- **WHO/RHR**
- **JHU/CCP**
- **UNFPA**
- **IPPF**
- **USAID**
- **MSH**
- **EngenderHealth**
- **FHI**
- **Population Council**
- **FIGO**
- **Alan Guttmacher Institute**
- **CDC**
- **NICHD/NIH**
- **IntraHealth**
- **JHPIEGO**
- **IRH Georgetown**
- **International Confederation of Midwives**
- **Pathfinder**
- **JSI**
- **URC/QAP**
- **RHRU**
- **East European Institute for Reproductive Health**

And more yet to join……

How the four Cornerstones contribute to Quality of Care?

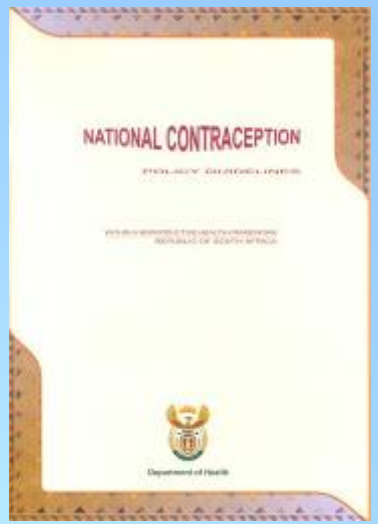
- Improve access
- Improve choice
- Improve safety
- Improve confidence of service providers and clients

Implementation of guidelines: example

WHO/WPRO Regional workshop to implement MEC guidance, Fiji 2000

- **Example of flexibility in interpretation of guidance:**
  Can women fully breastfeeding use progestogen-only contraceptives immediately post-partum?
- **MEC Recommendation: Category 3 until 6 weeks post-partum**

Implementation of guidelines

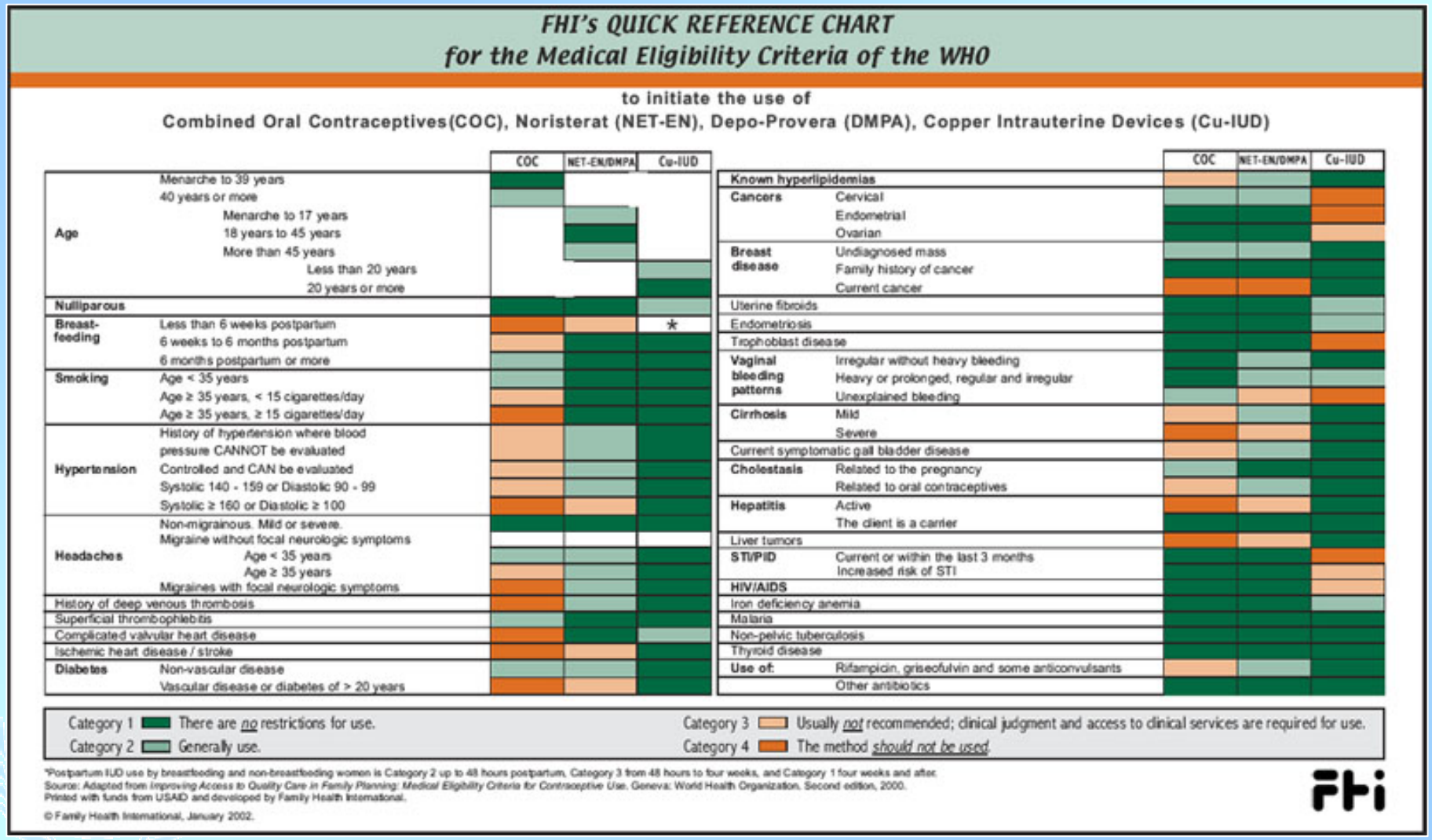


- **Integration into national guidelines / standards**

- **Used in popular guides**

- **Used to for national training**

Materials derived from the guidelines



FHI's QUICK REFERENCE CHART
for the Medical Eligibility Criteria of the WHO

to initiate the use of

Combined Oral Contraceptives(COC), Noristerat (NET-EN), Depo-Provera (DMPA), Copper Intrauterine Devices (Cu-IUD)

		COC	NET-EN/DMPA	Cu-IUD
Age	Menarche to 39 years	1		
	40 years or more	2		
	Menarche to 17 years		2	
	18 years to 45 years		1	
	More than 45 years		2	
	Less than 20 years			2
	20 years or more			1
Nulliparous		1	1	2
Breast-feeding	Less than 6 weeks postpartum	3	3	*
	6 weeks to 6 months postpartum	2	1	1
	6 months postpartum or more	2	1	1
Smoking	Age < 35 years	2	1	1
	Age ≥ 35 years, < 15 cigarettes/day	3	1	1
	Age ≥ 35 years, ≥ 15 cigarettes/day	4	1	1
Hypertension	History of hypertension where blood pressure CANNOT be evaluated	3	2	1
	Controlled and CAN be evaluated	3	2	1
	Systolic 140 - 159 or Diastolic 90 - 99	3	2	1
	Systolic ≥ 160 or Diastolic ≥ 100	4	3	1
Headaches	Non-migrainous. Mild or severe.	1	1	1
	Migraine without focal neurologic symptoms			
	Age < 35 years	2	2	1
	Age ≥ 35 years	3	2	1
	Migraines with focal neurologic symptoms	4	2	1
History of deep venous thrombosis		4	2	1
Superficial thrombophlebitis		2	1	1
Complicated valvular heart disease		4	1	2
Ischemic heart disease / stroke		4	3	1
Diabetes	Non-vascular disease	2	2	1
	Vascular disease or diabetes of > 20 years	4	3	1

		COC	NET-EN/DMPA	Cu-IUD
Known hyperlipidemias		3	2	1
Cancers	Cervical	2	2	4
	Endometrial	1	1	4
	Ovarian	1	1	3
Breast disease	Undiagnosed mass	2	2	1
	Family history of cancer	1	1	1
	Current cancer	4	4	1
Uterine fibroids		1	1	2
Endometriosis		1	1	2
Trophoblast disease		1	1	4
Vaginal bleeding patterns	Irregular without heavy bleeding	1	2	1
	Heavy or prolonged, regular and irregular	1	2	2
	Unexplained bleeding	2	3	4
Cirrhosis	Mild	3	2	1
	Severe	4	3	1
Current symptomatic gall bladder disease		3	2	1
Cholestasis	Related to the pregnancy	2	1	1
	Related to oral contraceptives	3	2	1
Hepatitis	Active	4	3	1
	The client is a carrier	1	1	1
Liver tumors		4	3	1
STI/PID	Current or within the last 3 months	1	1	4
	Increased risk of STI	1	1	3
HIV/AIDS		1	1	3
Iron deficiency anemia		1	1	2
Malaria		1	1	1
Non-pelvic tuberculosis		1	1	1
Thyroid disease		1	1	1
Use of:	Rifampicin, griseofulvin and some anticonvulsants	3	2	1
	Other antibiotics	1	1	1

Category 1 There are no restrictions for use.
Category 2 Generally use.
Category 3 Usually not recommended; clinical judgment and access to clinical services are required for use.
Category 4 The method should not be used.

*Postpartum IUD use by breastfeeding and non-breastfeeding women is Category 2 up to 48 hours postpartum, Category 3 from 48 hours to four weeks, and Category 1 four weeks and after.

Source: Adapted from *Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use*. Geneva: World Health Organization, Second edition, 2000.

Printed with funds from USAID and developed by Family Health International.

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Source: www.fhi.org/en/fp/fpother/elegibility/whomastercriteria.pdf